# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PATRICIA LYNNE CONWAY,
IAN LEWIS BROWN,
XIN WANG, and
RACHEL JANE LUCAS



Appeal No. 2007-0070
Application No. 09/889,085

ON BRIEF

Before SCHEINER, GREEN, and LEBOVITZ, Administrative Patent Judges.

LEBOVITZ, Administrative Patent Judge.

## DECISION ON APPEAL

This appeal involves claims to microbial preparations comprising microbes which have been cultured on resistant starch. The Examiner has rejected the claims as anticipated and obvious over prior art. There is also an obvious-type double patenting rejection. We have jurisdiction under 35 U.S.C. § 134. We affirm.

## Background

Probiotic microbes are microorganisms which, when ingested, benefit animal health by improving their intestinal microbial balance. Specification, page 1, lines 1-15.

They are incorporated into a wide variety of products, including, foods (e.g., yogurt) and pharmaceutical preparations. Id., page 1, lines 15-31; page 2, lines 1-5. "One problem with the inclusion of probiotic microorganisms into processed food products is that the microorganisms often cannot survive in the food product for any length of time." Id., page 2, lines 6-8.

"The present inventors have made the surprising discovery that the inclusion of ... resistant starch in the form of, or derived from, starches containing dietary fibre, in the growth medium for the microorganisms can increase growth and yield of the microorganisms, as well as increase the survival of microorganisms in microbial preparations or starter cultures and in food and feed products during production and over the shelf-life of these products, and improve rate of survival of the microbes during transit through the digestive tract." Id., page 2, lines 25-32.

## Discussion

### The claims

Claims 20-41 and 63-153 are pending. Answer, page 2. Claims 41 and 76-153 are on appeal; claims 20-40 and 63-75 have been withdrawn from consideration. Id. Four grounds of rejection are on appeal. Brief, page 4. These are: 1) claims 41, 76, 77, 79, 81, 88, 90-105, 109-120, 124-135, and 139-150 as anticipated; 2) claims 41 and 76-153 as anticipated; 3) claims 41 and 76-153 as obvious; and 4) 41 and 76-153 as obvious-type double-patenting. We affirm the rejections under 1), 3), and 4), and vacate the rejection under 2).

Within each rejection, the claims have been argued as a group. Accordingly, the claims stand or fall together in each grouping. We select the following claims as representative.

> 41. A microbial preparation having an increased survival/recovery rate in a product prepared by the process comprising growing or culturing microbes in a media based on or containing resistant starch in a manner such that when subsequently incorporated in a product the survival/recovery rate of the harvested microbes is increased as compared with the same microbes grown or cultured in a media without resistant starch, and harvesting the cultured microbes having an increased survival/recovery rate.
>
> 77. A microbial preparation comprising harvested microbes which have been grown or cultured in a media based on or containing resistant starch in a manner such that when subsequently incorporated in a product, the survival/recovery rate of the harvested microbes is increased as compared with the same microbes grown or cultured in a media without resistant starch, the product being selected from the group consisting of a food, feed, nutraceutical, pharmaceutical, biocontrol, and bioremediation product, wherein the resistant starch is type RS1, RS3, or RS4.
>
> 78. The microbial preparation according to claim 77 further comprising resistant starch.

Each of claims 41 and 77 are directed to microbial preparations which have been prepared by growing the microorganisms in media containing resistant starch and then harvesting the starch-fed microorganisms. Claim 78 is directed to the harvested microbial preparation which further comprises a resistant starch.

The harvested microorganisms are required to have an increased survival/recovery rate when incorporated into a product "as compared with the same microbes grown or cultured in a media without resistant starch." Claims 41 and 77. The claims do not recite a specific quantity of resistant starch that is present in the media. However, the specification indicates that it "can be used in growth media at a concentration of about 0.01 to 10% (w/w)." Specification, page 6, lines 18-19. Claims

41 and 77 also do not require a specific amount of increase in the survival/recovery rate as compared to microbes which have not been cultured in the presence of resistant starch.

Anticipation

1) Masuda

Claims 41, 76, 77, 79, 81, 88, 90-105, 109-120, 124-135, and 139-150 stand rejected under U.S.C. § 102(b) as anticipated by Masuda.[1]

Masuda describes a mixture of three bacteria strains, LB (e.g., Streptococcus faecalis), SB (e.g., Bacillus mesentericus), and BB (e.g., Clostridium butyricum). Masuda, column 2, lines 4-55; column 3, lines 3-13. The bacteria are cultivated in a culture medium of a protein and carbohydrate. Id., column 4, lines 1-15. The source of carbohydrate can be potato starch, corn starch, or soluble starch. Id., column 4, lines 31-33.

The Examiner argues that the bacterial strains disclosed in Masuda include the same strains which are disclosed and claimed (e.g., claims 96 and 99) in the instant application, and thus would be capable of being grown on substrates comprising resistant starch as required by the claims. Answer, page 4, lines 18-22. The Examiner states that the claimed requirement that the "survival/recovery rate" be increased in comparison to microbes cultured in a media without resistant starch is "relative" and consequently satisfied by Masuda's strains which are "characterized as having enhanced heat, dry and drug stability." Id., page 14, lines 13-17; see also page 4, lines

[1] Masuda, U.S. Patent No. 5,143,845, issued Sept. 1, 1992

12-16. The Examiner concludes that Masuda "discloses identical composition[s] comprising microbial preparations comprising identical microbes that are characterized by enhanced survival, viability and recovery as required for the claimed product," anticipating the claimed subject matter. Id., page 5, lines 6-8.

In addressing the product-by-process format of the claims, the Examiner states that "product-by-process claims are not limited to the manipulations of the recited steps, only to the final structure of the product obtained and the patentability of a product does not depend on its method of production." Id., page 14, lines 6-9. After reviewing the data in the specification, the Examiner concludes that Appellants have not established that the process steps recited in the claims impart "any structural differences between the final microbes and starting microbes with regard to those 'biochemical' changes as argued. The final bacteria are the same as the starting bacteria." Answer, page 11, lines 19-21.

Appellants assert that product-by process claims are an acceptable format for claiming an invention which may be difficult to otherwise define. Brief, page 6, lines 22-29. Citing The Manual of Patent Examining Procedure (MPEP) § 2113, they argue "'the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art.'" Id., page 6, lines 30-31. They state that the specification provides evidence that the claimed harvested microbes cultured on resistant starch "have improved survival and recovery compared to the same organisms harvested from media without resistant starch. (See each of Examples 1-11 and Figs. 1-14 corresponding thereto)," and thus differ from the microbes disclosed by Masuda. Id., page 7, lines 11-13.

To establish that Masuda does not culture bacteria on resistant starch, Appellants provided a declaration by Dr. Ian Brown, a co-inventor of the instant application, which they argue establishes that "there was no resistant starch in the microbial cultures of Masuda." Brief, page 6, lines 16-17. They also state: "The Masuda compositions were not cultured on resistant starch but were only said to have enhanced heat, dry and drug stability after spore formation! (Col. 2, lines 53-55, col. 5, lines 2-4) [.] Appellants' composition is not directed to microbial spores!" Id., page 7, lines 20-22 (emphasis removed).

A product-by-process claim is not statutory. Accordingly, we begin our analysis by summarizing the decisional case law on this claim format.

> A product-by-process claim is "one in which the product is defined at least in part in terms of the method or process by which it is made." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 158 n. [9 USPQ2d 1847] (1989) (quoting D. Chisum, Patents § 8.05, at 8-67 (1988)). While the patent statute does not provide for product-by-process claims, the courts have long recognized the appropriateness of such claims. See, e.g., In re Thorpe, 777 F.2d 695, 697 [227 USPQ 964] (Fed. Cir. 1985); In re Brown, 459 F.2d 531, 535 [173 USPQ 685] (C.C.P.A. 1972); In re Steppan, 394 F.2d 1013, 1018 [156 USPQ 143] (C.C.P.A. 1967). The purpose of product-by-process claims is to allow inventors to claim "an otherwise patentable product that resists definition by other than the process by which it is made." In re Thorpe, 777 F.2d at 697, [227 USPQ at 966]. Thus, an inventor will not be foreclosed from the benefits of the patent system simply because a product is difficult to describe in words, or its structure is insufficiently understood.

SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1315, 78 USPQ2d 1097, 1099 (Fed. Cir. 2006).

In this case, a microbial preparation is claimed by a process which comprises culturing the microbe in a media containing resistant starch and then harvesting the cultured microbes. The cultured microbes are claimed to have increased

survival/recovery rate as compared to the same microbes grown in media without resistant starch. "'[Even] though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. MPEP § 2113 (8th ed., Rev. 2, May 2004) (quoting In re Thorpe, 777 F.2d at 698).'" SmithKline Beecham at 439 F.3d at 1317, 78 USPQ2d at 1101. The Examiner has the initial burden of providing evidence that the product described by the prior art is the same product which is claimed. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Once a prima facie case has been established, the burden shifts to Appellants "to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980); In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

We find that there is sufficient evidence of record to establish a prima facie case of anticipation. This includes evidence that the microbes disclosed in Masuda comprise the same microbial strains utilized and claimed (e.g., claim 96 and 99) in the instant application and which were also cultured on potato starch, characterized in the specification as containing resistant starch. Specification, page 7, lines 14-16.

Although the Examiner observed that Masuda disclosed potato starch as a substrate for its bacteria (Answer, page 4, line 7; page 5, line 2), admitted by Appellants to contain resistant starch (Specification, page 7, line 16), she did not believe it

necessary to rely on this fact in setting forth the ground of rejection (Answer, page 14, line 3-7). Nonetheless, Appellants addressed the issue, providing a declaration by Dr. Ian Brown pursuant to 37 C.F.R. § 1.132 ("Declaration of Dr. Ian Brown") which they assert shows that resistant starch is not present in the potato starch media on which Masuda's bacteria were grown. Brief, page 6.

We have reviewed Dr. Brown's declaration and do not find it persuasive. According to the declarant,

> Rendleman, Biotechnol. Appl. Biochem. 31: 171-178 (2000) (Appendix B) describes that uncooked potato starch was only 10.9% degraded to G1 to G7 residues after 8 hours in the presence of alpha-amylase. (Table 2) [.] In contrast, potato starch which had been cooked at 100°C for 30 minutes was 88.6% degraded to G1 to G7 residues. (Table 3) [.] Thus, the cooking process of Masuda destroyed the potato starch granule so that the resultant material is no longer RS2 (uncooked starch).

Declaration of Dr. Ian Brown, ¶ 6. As we understand, if 88.6% is degraded, 11.4% would still remain which is present in some degree as resistant starch. This is inconsistent with Dr. Brown's conclusion that "Masuda makes clear (and those of skill in the art would recognize) that the potato starch compositions of Masuda are cooked in a manner such that no resistant starch would remain." Declaration of Dr. Ian Brown, ¶ 4. See also Declaration of Dr. Ian Brown, ¶ 7, stating that after autoclaving "Masuda examples are substantially free of resistant starch." Since claim 41 does not require the media to contain a particular quantity of resistant starch, we conclude that microbes grown in Masuda's basal media, even after autoclaving, would have been grown or cultured in a media containing resistant starch as recited in the claims.

We also do not find the declaration persuasive because the cooking conditions described in ¶ 6 which form the basis for Dr. Brown's conclusions, do not appear to be equivalent to autoclaving. For example, the cooking conditions do not describe heating at a pressure of "15 psig," which Dr. Brown describes as "standard autoclave conditions." Declaration of Dr. Ian Brown, ¶ 7. The Examiner also challenged Brown's conclusion that autoclaving would eliminate resistant starch, relying on disclosure in the specification admitting that "repeated autoclaving and rapid cooling can be used to increase the resistant starch content." Specification, page 5, lines 1-3. Answer, page 13, lines 15-19.

Masuda also describes microbes which have been cultured on resistant starch and then harvested. At column 4, lines 38-47, SB microbial strains are cultured in a basal media containing potato starch, which we have concluded (above) would have contained resistant starch. After proliferation, "the SB are separated (e.g., filtration) from the culture fluid." Id., column 4, lines 44-45. This satisfies the step recited in claim 41 of "harvesting the cultured microbes." Because the Examiner did not rely on this disclosure in the rejection of record, we designate this a new grounds of rejection in order to give Appellants the opportunity to respond to it. 37 C.F.R. § 41.50(b).

Having established prima facie anticipation, the burden properly shifted to Appellants to provide evidence that the claimed microbial preparation differs from the preparations described by Masuda. In re Oetiker, 977 F2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In Figs. 4, 5, 6, 7, 9, 13, 14 of the specification, data is shown for the survival/recovery of starch-fed microbes in probiotic and yogurt drinks. These experiments are described in Examples 4 and 5. Specification, page 12, line 23-

page 13, line 2. Contrary to the Examiner's conclusion, we agree with Appellants that this data generally shows that the particular resistant starch-fed microbial strains show increased "survival/recovery" in food products as compared to the same strains grown in the absence of resistant starch.

The Examiner argues that Figs. 4-9 "demonstrate that after 5-6 days there would be no viable cells and, thus, no survival and recovery of microbial preparations for all tested substrates and/or products." Answer, page 12, lines 19-21. However, as Appellants assert, the fact that the starch-fed microbes eventually die does not conflict with the data that these strains show improved survival during the course of the experiments. Reply Brief, page 6. For example, Fig. 7 shows that microbes grown in the absence of resistant starch (glucose) were not viable at the end of one day, while the viability of resistant starch-fed microbes was increased to 2 and 5 days, respectively, depending on the type of starch diet. We have not addressed the Examiner's concerns with Figs. 1 and 3 (Answer, pages 12-13) since these were derived from experiments which did not address the growth and viability of the microbial strains in a product as required by claim 41.

We agree with Appellants that at least for the particular microbial strains tested in the specification, the evidence is sufficient to support their assertion that the product-by-process steps distinguish these resistant starch-fed strains from strains not fed resistant starch. However, we do not find this evidence adequate to rebut the prima facie case for the entire scope of the claim. First, Masuda's strains are cultured in media comprising resistant starch, and therefore would inherently possess the claimed characteristics. Secondly, claim 41 is drawn to a "microbial preparation," but does not

require the microbe to be a particular type or strain. However, the data in the specification which shows improved survival and recovery is for one microbial strain, Bifidobacterium strain C. Thus, Appellants have come forward with evidence only for this single strain. Claim 41 is broader and still reads on anticipatory species described in Masuda.

As for Appellants' argument that Masuda's preparations contain bacterial spores, we agree with the Examiner that the claims do not exclude the microbes from being in the form of spores. Answer, page 15, line 2.

For the foregoing reasons, we affirm the rejection of claim 41. Because claims 76, 77, 79, 81, 88, 90-105, 109-120, 124-135, and 139-150 were not separately argued, these claims fall with claim 41.

2) Brown

Claims 41 and 76-153 stand rejected under 35 U.S.C. § 102(b) as anticipated by Brown '050[2] in light of evidence by McNaught.[3]

It does not appear that Brown '050 qualifies as prior art under § 102(b) to the instant application. The foreign priority date of the application is Jan. 14, 1999 and the § 371 date is Jan. 14, 2000, both dates which are prior to the May 9, 2000 publication date of Brown '050. At the same time, we note that Brown '050 is based on PCT Application WO96/08261, published Mar. 21, 1996, which appears to qualify as § 102(b) prior art. Accordingly, we vacate this rejection. If prosecution is resumed, we suggest

[2] Brown et al. (Brown '050), U.S. Patent No. 6,060,050, issued May 9, 2000
[3] McNaught et al. (McNaught), U.S. Patent No. 5,714,600, issued Feb. 3, 1998

that the Examiner determine whether the instant claims are more properly unpatentable under § 102(b) over WO96/08261.

With regard to WO96/08261, we observe that it has the same disclosure as the Brown '050 patent which was cited by the Examiner to anticipate the claimed subject matter. Fig. 9, which the Examiner cites for teaching microbes cultured on resistant starch, is also present in WO96/08261. In considering whether a rejection is appropriate, the Examiner should also determine whether the harvesting step required by claim 78 properly distinguishes a bacterial culture of Fig. 9 comprising: 1) bifido-bacteria microbes grown in the presence of resistant starch and 2) starch-containing media.

3) Obviousness

Claims 41 and 76-153 stand rejected under 35 U.S.C. § 103(a) as obvious over Masuda taken with Brown '050, Brown (Food Australia),[4] and McNaught.

Masuda was described above.

The Examiner cites Brown (Food Australia) for its teaching to incorporate resistant starch into products which contain probiotic bacteria to improve their viability during processing, storage, and transit through the gastrointestinal tract. Answer, page 8. "The high amylose maize [resistant] starch, Culture-Pro™, displayed an ability to enhance survival of the bifidobacteria under acid conditions similar to those experienced in the stomach (Table 6) or in the presence of bile acids (Table 7) (Wang & others

[4] Brown et al. (Brown (Food Australia)), "High amylose maize starch as a versatile prebiotic for use with probiotic bacteria," Food Australia, Vol. 50, No. 12, pp. 603-610 (1998).

1998d)." Brown (Food Australia), page 607. Brown (Food Australia) also describes the value of resistant starch in enhancing probiotic bacteria when included in a food product.

> This method of maintaining the viability of bifidobacteria can be utilised in the preparation of commercial mild yoghurts and offers the advantages of naturally maintaining the viability of the probiotic bacteria during processing and storage. Figure 2 refers to an experiment where the inclusion of 1%w/v of granular [Hi-maize™ resistant] starch resulted in a significant improvement in the viability of both the Lactobacillus acidophilus and Bifidobacterium sp. during the six week storage period of using the yoghurt (Anon 1997).

Id., page 609, column 1.

McNaught "is relied upon to demonstrate that physically and/or chemically modified resistant starch (col.7, lines 13-15) including maize starch having high amylose contents of at least 40-90% (col. 2, lines 63-67) are available in the prior art and they have been suggested for various compositions including foods and other industrial products (col. 1, line 24)." Answer, page 8.

According to the Examiner, it would have been obvious to one of ordinary skill in the art to have combined a resistant starch with the probiotic bacteria of Masuda "for the expected benefits related to the improved viability and to stress resistance of probiotic cultures (Brown [Food Australia] et al.)." Answer, pages 8-9.

Appellants contend that there is no rationale for combining the references. They argue: 1) Masuda is directed to spore formation and symbiotic microbe mixtures, not culture of microbes on resistant starch (Brief, page 9); and 2) Brown (Food Australia) teaches that starch protects microbes in the gut which "differs from the microbes of the present invention which have enhanced resistance whether or not resistant starch is present!" Brief, pages 10.

Obviousness requires assessing "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). To make this determination, we are instructed by the Federal Circuit to "consider whether a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so. Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.3d 1120, 1124 (Fed. Cir. 2000)." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80USPQ2d 1641, 1645 (Fed. Cir. 2006). When, as here, all claim limitations are found in the prior art references, the factfinder must determine "[w]hat the prior art teaches, whether it teaches away from the claimed invention, and whether it motivates a combination of teachings from different references." In re Fulton, 391 F.3d 1195, 1199-1200, 73 USPQ2d 1141, 1144 (Fed. Cir. 2004).

Because both Examiner and Appellants focus their arguments on the claims directed to the resistant starch-fed microbes and resistant starch, we have selected claim 78 as representative for the purpose of deciding this ground of rejection.

Brown (Food Australia) identifies two problems encountered with the use of probiotic bacteria. First, transit through the gastrointestinal tract can reduce the viability of probiotic bacteria. Brown (Food Australia), page 607, column 2. Secondly, the proper number of bacteria in products to which they have been added must be maintained in order to provide a physiological probiotic effect. Id., page 608. The

addition of resistant starch to products containing probiotic bacteria is described by Brown (Food Australia) to address these issues. Id., pages 604 and 610. Since Masuda's strains are for the same uses that Brown's bacteria are for (e.g., "for improving human health"; Masuda, column 1, line 38), and include some of the same strains (e.g., lactobacillis), we concur with the Examiner that the skilled worker would have been motivated with a reasonable expectation of success to have applied Brown's (Food Australia) approach of adding resistant starch for the expected benefit in improving viability during processing, storage, and gastrointestinal transit. For the reasons discussed above under the § 102(b) rejection over Masuda, we conclude that Masuda discloses microbial strains which satisfy the requirements for the claimed harvested microbes.

Appellants argue that the protective effect observed by Brown is "dependent upon the presence of the resistant starch," not the result of the microbe's past history of being cultured on resistant starch. See Brief, page 10. They urge that this effect does not require the presence of starch which have enhanced resistance whether or not starch is present. Id. We do not find this argument persuasive. While the presence of starch may not be necessary, Appellants have presented no evidence that it would be a detriment.

As for Appellants' argument (Brief, page 9) that Masuda is directed to spore formation, we note that the claims do not exclude the microbes from being in the form of spores. Similarly, the claims do not exclude the presence of other bacteria; accordingly, we find no merit in Appellants' argument that the Masuda describes symbiotic microbe mixtures. Id.

In sum, we find that the Examiner has provided adequate evidence to establish prima facie obviousness of claim 78. Claims 41, 76, 77, and 79-153 fall with claim 78 because they were not separately argued.

4) Obvious-type double-patenting over Brown '350

Claims 41 and 76-153 stand rejected under the judicially-created doctrine of obvious-type double patenting as being unpatentable over claims 1-12 of Brown '350.[5]

The Examiner argues that the conflicting claims in the instant application and the claims of Brown '350 are not patentably distinct from each other because both cover "1) probiotic microorganisms and 2) resistant starch." Answer, page 10. The Examiner also states that the microbes and substrates which are disclosed and claimed in the instant application are identical to those which are claimed in Brown '350. Id., page 10, lines 12-16. Although Brown '350 claims require an oligosaccharide which is not recited by the instant claims, the Examiner asserts that the claimed subject matter is an obvious variant of Brown '350 claims because "they encompass ... food products including confectionary, biscuits, desserts or flavored drinks that do not exclude the use of oligosaccharides ... and, therefore, are reasonably expected to comprises at least some amounts of oligosaccharides." Id.

Appellants argue that the rejection should "be reversed because the microbes of Brown '350 are not cultured on media containing resistant starch and as a result do not have the improved survival/recovery properties of the claimed microbes." Brief, page 11.

[5] Brown et al. (Brown '350), U.S. Patent No. 6,221,350, issued Apr. 24, 2001

We affirm this rejection. Appellants have not shown that the product-by-process steps confer the claimed increased survival/recovery rate on all microbes which fall within the scope of claim 41. As discussed above in the rejection over Masuda under § 102(b), a showing has only been provided for Bifidobacterium strain C; consequently, the instant claims still cover microbes which are within the scope of claims 1-12 of Brown '350.

Other Issues

If prosecution of this application on the merits is resumed, we encourage the Examiner to consider the following additional issues:

1) Example 1 at column 3, lines 15-25 of Masuda describes a composition which appears to contain (a) a mixture of three bacteria which were cultured in a potato starch medium (e.g., column 2, lines 44-55) and (b) potato starch (column 3, line 24). The Examiner should determine whether this disclosure anticipates any of the claims.

2) Brown (Food Australia) describes microbes which are cultured in a media containing a resistant starch. The Examiner should consider whether such microbes (which after being grown in the media for a certain period of time would have the claimed increased survival/recovery rate and would further comprise resistant starch as required by claim 78) would be substantially the same as the claimed product-by-process microbes, even in the absence of having been subjected to a harvesting step.

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz.

Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED/§ 41.50(b)

Toni R. Scheiner )
Administrative Patent Judge )
)
)
) BOARD OF PATENT
Lora M. Green )
Administrative Patent Judge ) APPEALS AND
)
) INTERFERENCES
)
Richard M. Lebovitz )
Administrative Patent Judge )

RML/jlb

Jeffrey S. Sharp
Marshall, Gerstein and Borun
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6357